

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

NOT FOR PUBLICATION

<p>AZURITY PHARMACEUTICALS, INC.,</p> <p style="text-align: center;">Plaintiff,</p> <p style="text-align: center;">v.</p> <p>AMNEAL PHARMACEUTICALS, LLC,</p> <p style="text-align: center;">Defendant.</p>	<p style="text-align: center;">Civ. No. 21-08717 (GC)</p> <p style="text-align: center;">CLAIM CONSTRUCTION OPINION AND ORDER</p>
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CASTNER, District Judge

THIS MATTER comes before the Court on the Joint Claim Construction and Prehearing Statement regarding U.S. Patent No. 10,799,453 (“the ’453 Patent”) submitted by Plaintiff Azurity Pharmaceuticals, Inc. (“Azurity”) and Defendant Amneal Pharmaceuticals LLC (“Amneal”) pursuant to L. Pat. R. 4.3. (ECF No. 55.) On January 13, 2022, Azurity and Amneal filed opening briefs. (ECF Nos. 56, 57.) On March 18, 2022, Azurity and Amneal filed response briefs. (ECF Nos. 63, 64.) On March 18, 2022, Amneal also filed a Motion to Strike the Declaration of Dr. Steven Little. (ECF No. 65.)

The parties dispute whether a list of steps in claim 1 of the ’453 Patent, indicated by roman numerals (i), (ii), and (iii) — needs to be performed in the order listed. (Joint Prehr’g Stmt., Ex. A, ECF No. 55.) On June 8, 2022, pursuant to L. Pat. R. 4.6, the Court held a *Markman* hearing to construe the claim term. This claim term is construed below.

I. BACKGROUND

A. Procedural Background

This case arises out of Amneal’s filing of an Abbreviated New Drug Application (“ANDA”) with the Food and Drug Administration (“FDA”) to seek approval to market a generic version of the pharmaceutical product Katerzia®. (Joint Prehr’g Stmt. 2.) Katerzia®, a brand name pharmaceutical drug, is an oral, liquid formulation of amlodipine used to treat hypertension and coronary artery disease. (See Compl. ¶¶ 1, 7, ECF No. 1.) Azurity, which holds the New Drug Application (“NDA”) for Katerzia®, alleges that Amneal’s ANDA infringes on four patents, including the ’453 Patent, that cover Azurity’s Katerzia® product. (*Id.* ¶¶ 8, 25–28.)

To market and sell Katerzia®, Azurity listed the ’453 Patent in the FDA’s Approved Drug Products with Therapeutic Equivalence Applications, commonly known as the Orange Book. See 21 U.S.C. § 355(b)(1), (c)(2). Thereafter, Amneal filed its ANDA with the FDA to seek approval to market a generic version of Katerzia®. See 21 U.S.C. § 355(j)(1). Accordingly, pursuant to 21 U.S.C. §§ 355(j)(5)(B)(iii), Azurity initiated this suit against Amneal because Amneal’s request to market the generic version of Katerzia® was done prior to the expiration of the ’453 Patent. (Compl. ¶ 25.)

B. The ’453 Patent

The ’453 Patent is the only patent at issue in this claim construction. (Joint Prehr’g Stmt. 3.)¹ The ’453 Patent was filed on April 11, 2019 as Application No. 16/381,575. (See U.S. Patent No. 10,799,453 (filed Apr. 11, 2019), ECF No. 1-2.) The ’453 Patent is entitled “Amlodipine Formulations.” (*Id.* col. 1 l. 1.) Amlodipine is a “calcium channel blocker,” which means that it

¹ The other patents are United States Patent Nos. 10,695,329, 10,894,039, and 10,952,998. (Compl. ¶ 1.)

“affects the movement of calcium into the cells of the heart and blood vessels” and thus, “relaxes blood vessels and increases the supply of blood and oxygen to the heart while reducing its workload.” (*Id.* col. 1 l. 37–41.)

The '453 Patent is directed to the formulation of a liquid form of amlodipine. (*See id.* col. 17 l. 24–25.) Historically, amlodipine was administered in tablet form, but the liquid formulations of amlodipine are “advantageous over conventional solid dosage administration of amlodipine ranging from ease of administration, accuracy of dosing, accessibility to additional patient populations such as to children and the elderly, and an increased patient compliance to medication.” (*Id.* col. 17 l. 27–32.)

C. *Claim One*

Claim 1 contains the only disputed claim term in this claim construction dispute. (Pl.’s Opening Br. 1, ECF No. 56; Def.’s Opening Br. 1, ECF No. 57.)²

Claim 1 of the '453 Patent claims the following:

A suspension comprising particles comprising amlodipine benzoate and having a median diameter D50 value of between about 5µm and about 40 µm as measured by a light scattering particle size analyzer, and the said suspension is made by a process comprising:

- (i) providing an aqueous mixture comprising amlodipine besylate;
- (ii) adding sodium benzoate to the aqueous mixture to form a first mixture; and
- (iii) subjecting the first mixture to ultrasonic agitation at a frequency of between about 20 kHz and about 100 kHz, thereby forming a second mixture comprising amlodipine benzoate.

('453 Patent col. 77 l. 44–56.)

² The parties agree that the disputed claim term and corresponding claim “include all asserted claims that depend directly or indirectly from the listed claim.” (Joint Prehr’g Stmt., Ex. A A-1 n.3.

The parties dispute whether the steps listed in claim 1 of the '453 Patent must be performed in the order in which they appear in claim 1. The parties assert the following proposed claim construction:

Azurity's Proposed Construction	The limitations recited in claim 1 do not require a specific sequence.
Amneal's Proposed Construction	Steps (i), (ii), and (iii) must be performed in the order recited.

II. LEGAL STANDARD

The meaning and scope of patent claims are questions of law to be decided by the court. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). “It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal citation and quotation marks omitted). “[T]here is no magic formula or catechism for conducting claim construction.” *Id.* at 1324. Instead, the Court is free to attach the appropriate weight to appropriate sources “in light of the statutes and policies that inform patent law.” *Id.* (citing *Vitronics Corp. v. Conceptor, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). “Claim construction begins with the intrinsic evidence of the patent—the claims, the specification, and the prosecution history—and may require consultation of extrinsic evidence to understand the state of the art during the relevant time period.” *Merck Sharp & Dohme Corp. v. Teva Pharms. USA, Inc.*, 2019 WL 943532, at *2 (D.N.J. Feb. 26, 2019); *see also Phillips*, 415 F.3d at 1314–17.

First, the court “looks to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention.” *Vitronics Corp.*, 90 F.3d at 1582. The “words of a claim ‘are generally given their ordinary and customary meaning,’” which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e.,

as of the effective filing date of the patent application.” *Phillips*, 415 F.3d. at 1312–13 (quoting *Vitronics Corp.*, 90 F.3d at 1582). A person of ordinary skill in the art (“POSA”) “is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.” *Id.* at 1313 (citing *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998)). Accordingly, “the claims themselves provide substantial guidance as to the meaning of particular claim terms,” and a court may look to “the context in which a term is used in the asserted claim” and “other claims of the patent in question, both asserted and unasserted.” *See id.* at 1314.

Second, the specification is “always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Vitronics Corp.*, 90 F.3d at 1582; *see also Phillips*, 415 F.3d at 1315 (noting that claims “are part of ‘a fully integrated written instrument,’ and ‘must be read in view of the specification, of which they are a part’”) (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978–79 (Fed. Cir. 1995), *aff’d*, 517 U.S. 370 (1996)). “Although words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history.” *Vitronics Corp.*, 90 F.3d at 1582. However, while “[t]he written description and other parts of the specification [] may shed contextual light on the plain and ordinary meaning [], they cannot be used to narrow a claim term to deviate from the plain and ordinary meaning unless the inventor acted as his own lexicographer or intentionally disclaimed or disavowed claim scope.” *Aventis Pharms. Inc. v. Amino Chemicals Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013).

Third, a court “should also consider the patent’s prosecution history, if it is in evidence.” *Markman*, 52 F.3d at 980. “This history contains the complete record of all the proceedings before the Patent and Trademark Office [(“PTO”)], including any express representations made by the applicant regarding the scope of the claims.” *Vitronics Corp.*, 90 F.3d at 1582. “A patent’s prosecution history, though less useful for claim construction purposes than the claim language and written description, plays various roles in resolving uncertainties about claim scope.” *Mass. Inst. of Tech. v. Shire Pharms., Inc.*, 839 F.3d 1111, 1118 (Fed. Cir. 2016) (internal quotation marks and citations omitted). The prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention. *Phillips*, 415 F.3d at 1317. For example, the prosecution history may “limit[] the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.” *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995) (citation omitted). However, “because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes.” *Phillips*, 415 F.3d at 1317.

Finally, in some cases, the “district court will need to look beyond the patent’s intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period.” *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331 (2015). “Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980. However, “[i]n those cases where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper.” *Vitronics Corp.*, 90 F.3d at 1583. “When an analysis of *intrinsic*

evidence resolves any ambiguity in a disputed claim term, it is improper to rely on extrinsic evidence to contradict the meaning so ascertained.” *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1367 (Fed. Cir. 2003) (emphasis in original). “Extrinsic evidence [] cannot be used to alter a claim construction dictated by a proper analysis of the intrinsic evidence.” *On-Line Tech. v. Bodenseewerk Perkin-Elmer*, 386 F.3d 1133, 1139 (Fed. Cir. 2004) (citations omitted).

III. PARTIES’ ARGUMENTS

The parties dispute whether the steps described in roman numerals (i), (ii), and (iii) of claim 1 must be performed in the order written. Azurity asserts that “[t]he limitations recited in claim 1 do not require a specific sequence.” (Joint Prehr’g Stmt., Ex. A A-1.) Amneal asserts that “[s]teps (i), (ii), and (iii) must be performed in the order recited.” (*Id.*) Both parties argue that the intrinsic evidence — the plain language of the claim, the specification, and prosecution history — support their respective positions. (*See* Pl.’s Opening Br. 7; Def.’s Opening Br. 2.) Azurity also submits a Declaration of Dr. Steven Little (the “Little Declaration”) to support its construction that ordering is not required. (*See* Pl.’s Opening Br. 8–9; Little Decl. ¶¶ 36–43, ECF No. 56-1.) Amneal opposes the Court’s consideration of the Little Declaration in the construction of claim 1. (Def.’s Responsive Br. 3–4, ECF No. 63.) The Court summarizes the parties’ positions below.

A. *Plaintiff Azurity’s Argument*

Regarding the claim language, Azurity argues, “[a]lthough the actions of claim 1 are identified by roman numerals (i)–(iii), this alone is insufficient to mandate that these actions be performed in a recited order.” (Pl.’s Responsive Br. 6, ECF No. 64.) Azurity argues that the roman numerals in claim 1 do not “imply a specific order, but [] allow easy reference to the specific steps or actions in the dependent claims.” (Pl.’s Opening Br. 7 (citing Claim 5, which refers to the “aqueous mixture of step (i)”); Patent ’453 col. 78 l. 29–32.) Additionally, Azurity notes that the

use of the word “comprising” in claim 1 “supports alternative sequences [because] it allows for the occurrence of additional actions to break up the alleged sequence of (i)–(iii).” (Pl.’s Responsive Br. 6.) In sum, Azurity contends, the language of claim 1 does not “require by logic or grammar that actions (i)–(iii) *must* be performed in the order as recited.” (*Id.* at 7 (emphasis in original).)

Azurity further asserts that “the specification does not teach that the actions of [c]laim 1 need be performed in a specific sequence.” (Pl.’s Opening Br. 7.) Rather, Azurity argues, the specification “illustrates how the actions in [c]laim 1 can be performed in a different order and form an amlodipine benzoate suspension having particles with a median diameter between about 5 and 40 microns, as required by the claim.” (*Id.*) For example, Azurity points to Examples 2, 4, and 6, which discuss the making of batches where sonication (step (iii)) began before the addition of sodium benzoate (step (ii)).³ (*Id.* at 7–8 (citing ’453 Patent col. 69 l. 60–col. 70 l. 30, col. 71 l. 62–63, col. 72 l. 49–50, col. 72 l. 6–9); *see also* Hr’g Tr. 9:12–11:18, ECF No. 86 (asserting that Example 2 contemplates that step (iii) occurs prior to step (ii)); Pl.’s Responsive Br. 8 (noting that the “specification explicitly contemplates performing the ultrasonic agitation before, during, and after the amlodipine besylate and sodium benzoate are mixed together”).)

Azurity also points to portions of the prosecution history to support its argument that the steps in claim 1 may be performed in any order. In the patentee’s Response to the Non-Final Office Action dated June 25, 2019, the patentee responded to the United States Patent Office’s “allegations that ‘the specification [does] not teach or suggest how one can control the particle size to get the desired results.’” (The Response to the Non-Final Office Action dated June 25, 2019,

³ Ultrasonic agitation is also referred to as “sonication.” (*See* ’453 Patent col. 41 l. 44–47.)

Appl. No. 16/381,575, AZU_KAT_0001113, Pl.’s Ex. B, ECF No. 56-4 (hereinafter, “Response to the Non-Final Office Action dated June 25, 2019.”) The patentee noted, “a skilled artisan would appreciate that parameters such as the duration of the sonication, the frequency of the sonification [sic], and *the addition sequence of the salt forming agents* and surfactants *can be adjusted* to control the particle size.” (Response to the Non-Final Office Action dated June 25, 2019, AZU_KAT_0001113 (emphasis added).) According to Azurity, “salt forming agents” include both amlodipine besylate and sodium benzoate; thus, when the patentee noted in the Response that the “addition sequence of the salt forming agents . . . could be adjusted[,] . . . this supports [Azurity’s] position that you could add the sodium benzoate first.” (Hr’g Tr. 16:16–17:13.)

Azurity also argues that the prosecution history supports its construction of claim 1 because, “in the Notice of Allowability, the examiner characterized the Allowable Subject Matter as ‘suspensions comprising particles having a median diameter of 5-40 μm and comprising amlodipine benzoate and other additives, wherein amlodipine benzoate is produced *in situ* by mixing amlodipine besylate, sodium benzoate and other additives, and wherein said suspensions are stable at 25 °C for at least 12 months.” (Pl.’s Responsive Br. 10–11; Not. of Allowability, Pl.’s Ex. B, AZU_KAT0001965, ECF No. 56-6.) According to Azurity, this indicates that “the examiner understood that the order of the recited actions in claim 1 was not a critical part of the invention, and the claim should not be restricted to require a particular order now.” (Pl.’s Responsive Br. 10–11.)

In response to Amneal’s argument that the prosecution history demonstrates that the patentee and examiner embraced a “sequential rubric” of the claim because of the patentee’s amendment to claims during the application process to clarify when certain additions should be made, *see infra* III.B, Azurity argues that “[t]he use of ‘first’ and ‘second’ is simply used to

distinguish the two surfactants and is inconsequential to the order of actions in claim 1.” (Pl.’s Responsive Br. 9–10.) Azurity also notes that the claims that Amneal asserts embrace this “sequential rubric,” “are not independent claims and [the] [a]pplicant’s amendments have nothing to do with the sequence of actions (i), (ii), and (iii),” and further, that two of those claims were ultimately dropped from the prosecution. (*Id.* at 8–9.)

Finally, Azurity submits extrinsic evidence, the Little Declaration, to support the assertion that a POSA would understand that steps (i), (ii), and (iii) in claim 1 do not need to be performed in a specific sequence. (Pl.’s Opening Br. 8–9; Little Decl. ¶¶ 36–43.) Azurity opposes Amneal’s Motion to Strike. (ECF No. 72.)

B. *Defendant Amneal’s Argument*

Amneal asserts that “process claims — like the ones at issue here — ‘require an ordering of steps when the claim language, as a matter of logic or grammar, requires that the steps be performed in the order written, or the specification directly or implicitly requires’ an order of steps.” (Def.’s Opening Br. 2 (quoting *Mformation Techs., Inc. v. Research in Motion Ltd.*, 764 F.3d 1392, 1398–99 (Fed. Cir. 2014)).) Looking to the claim language, Amneal argues, it is “well-established law [that,] where the language of a step refers to the result of the prior step, the steps must be performed in order.” (*Id.* at 3.) Amneal asserts that here, “step (i) provides the ‘aqueous mixture,’ [] step (ii) adds sodium benzoate to that very ‘aqueous mixture’ to form a ‘first mixture,’” and “[s]tep (iii) subjects that very same ‘first mixture’ to ultrasonic agitation.” (*Id.*) Amneal argues that, because step (ii) refers to “the aqueous mixture,” the “only possible antecedent basis is the ‘aqueous mixture’ provided in step (i),” and because “step (iii) requires ‘subjecting the first mixture to ultrasonic agitation,’ . . . [t]he only possible antecedent basis for ‘the first mixture’ in step (iii) is the ‘first mixture’ formed in step (ii).” (*Id.* at 3–4 (citing *Wi-Lan, Inc. v. Apple, Inc.*,

811 F.3d 455, 462–63 (Fed. Cir. 2016) and *Chiesi USA Inc. v. MSN Pharmaceuticals Inc.*, 2021 WL 4843806, at 2–3 (D.N.J. Oct. 18, 2021)).) Thus, the law “compels” that the steps be performed in the order written because “steps (i), (ii), and (iii) are sequential on their face” and “[e]ach step is the logical and grammatical precursor for the subsequent step.” (*Id.* at 3.)

Amneal contends that, even if the Court looks beyond the claim language, the specification “also supports Amneal’s proposed construction because it repeatedly and uniformly uses the same operative logic and grammar used in the claims.” (*Id.* at 4.) Amneal argues that the claim does not prohibit other steps from occurring in between the listed steps, as long as steps (i), (ii), and (iii) occur in that order. (Hr’g Tr. 35:20–36:3.) Thus, even in Example 2, where the sonication (step (iii)) begins before the addition of sodium benzoate (step (ii)), the sonication still continues “for 10 minutes after that addition,” and thus, the step (iii) sonication still occurs after the step (ii) addition of sodium benzoate. (*See* Def.’s Br. 5–6 (citing Examples 2, 3, 4, 5, and 7).)

With respect to prosecution history, Amneal asserts that the “prosecution history of the ’453 [P]atent provides little additional guidance on the order of the recited process,” but there is “[o]ne exchange” that “suggests that both the examiner and the applicants understood the sequential nature of the process steps.” (Def.’s Opening Br. 6.) During the application process, the patent examiner rejected claims 16, 29, and 30 as incomplete for omitting essential steps. (Detailed Appl., Def.’s Ex. A, AMNKAT0020296, ECF No. 58-1.) The omissions were, “[c]laims 16, 29 and 30 disclose the presence/use of additional components in the claimed suspensions, but [did] not clarify at what stages/steps of the claimed method said additives should be included in the claimed suspension.” (*Id.*) In the Response to the Final Office Action dated December 31, 2019, the patentee amended claim 16 to state that “a second surfactant” was added “into the second mixture,” (*see id.* AMKAT20335), and Claims 29 and 30 to state that additional components were

introduced by “adding the second mixture into a third mixture,” (*see id.* AMKAT0020336–37). Amneal asserts that this exchange shows that the examiner and applicants both understood the recited processes as sequences of steps. (Def.’s Opening Br. 7.)

Amneal argues that the Court does not need to consider extrinsic evidence and moves to strike the Little Declaration. (Def.’s Responsive Br. 3–4; Mot. to Strike 1–2, ECF No. 65-1.)

IV. DISCUSSION

A. *Person Having Ordinary Skill in the Art*

Claims are construed from the vantage point of a POSA at the time of the invention. *Phillips*, 415 F.3d at 1313. Before the Court construes the claims in light of the specification, “it must establish the level of skill that a POSA possessed at the time of the invention.” *Supernus Pharms., Inc. v. Actavis Inc.*, 2016 WL 901837, at *2 (D.N.J. Mar. 9, 2016) (citing *AllVoice Computing PLC v. Nuance Commc’ns, Inc.*, 504 F.3d 1236, 1240 (Fed. Cir. 2007)). Here, Azurity provided the following definition for a POSA:

A POSA in the relevant field would be a person that has: (i) a Ph.D. in formulation relevant pharmaceutical science, chemistry, or a similar subject, with minimal post-degree experience in developing processes for manufacturing pharmaceutical products; or (ii) at a minimum a bachelor’s degree in pharmacy, pharmaceutical science, chemistry, chemical engineering, or a similar subject, with at least five years of post-degree practical experience in developing processes for manufacturing pharmaceutical products. A POSA would also have experience with pharmaceutical excipients as applied to their selection and use in drug formulations. With regard to the therapeutic application of the invention, a POSA would routinely collaborate with a medical doctor with experience treating hypertension and other cardiovascular conditions—particularly in pediatric patients—or a clinical pharmacologist.

(Pl.’s Opening Br. 6.)

At the *Markman* hearing, Amneal argued that the Court need not make a POSA determination because “this case should be decided on the law of document interpretation.” (Hr’g

Tr. 44:1–3.) Amneal also noted that it did not object to the POSA definition provided by Azurity. (*See id.* at 44:3–5.) As discussed herein, the Court does not decide this claim construction dispute solely on document interpretation, but rather assesses the parties’ arguments regarding the specification as well. *See infra* IV.C. Accordingly, the Court defines a POSA according to the un-objected to definition provided by Azurity. *See AllVoice Computing PLC*, 504 F. 3d at 1240 (adopting one party’s POSA definition where the other party “did not pose a different definition nor dispute the above definition”).

B. *Process Claims*

When construing a claim covering a process or method, the Federal Circuit has stated, “as a general rule, ‘[u]nless the steps of a method [claim] actually recite an order, the steps are not ordinarily construed to require one.’” *Mformation Techs., Inc.*, 764 F.3d at 1398 (quoting *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1342 (Fed. Cir. 2001)) (alterations in original). “However, a claim ‘requires an ordering of steps when the claim language, as a matter of logic or grammar, requires that the steps be performed in the order written, or the specification directly or implicitly requires’ an order of steps.” *Id.* (quoting *TALtech Ltd. v. Esquel Apparel, Inc.*, 279 F. App’x 974, 978 (Fed. Cir. 2008)).

The Federal Circuit has “recite[d] a two-part test for determining if the steps of a method claim that do not otherwise recite an order, must nonetheless be performed in the order in which they are written.” *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1369 (Fed. Cir. 2003). “First, [the court] look[s] to the claim language to determine if, as a matter of logic or grammar, they must be performed in the order written.” *Id.* (citing *Interactive Gift Express, Inc.*, 256 F.3d at 1343). “If not, [the court] next look[s] to the rest of the specification to determine whether it ‘directly or implicitly requires such a narrow construction.’” *Id.* at 1370 (quoting *Interactive Gift*

Express, Inc., 256 F.3d at 1343). If the specification does not directly or implicitly require such a narrow construction, “the sequence in which such steps are written is not a requirement.” *Id.* Additionally, when considering the specification, “particular embodiments appearing in the written description will not be used to limit claim language that has broader effect . . . And, even where a patent describes only a single embodiment, claims will not be ‘read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using ‘words or expressions of manifest exclusion or restriction.’” *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1117 (Fed. Cir. 2004) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (quoting *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324 (Fed. Cir. 2002))).

C. *Claim Construction*

The Court construes claim 1 according to the intrinsic evidence, beginning with the claim language, then specification, and finally, prosecution history. The Court then addresses the dispute over the extrinsic evidence.

1. Claim Language

Before reaching the language of the steps themselves, the Court addresses the parties’ arguments regarding the use of the word “comprising” in claim 1. Azurity asserts that the use of “comprising” in claim 1 “supports alternative sequences [because] it allows for the occurrence of additional actions to break up the alleged sequence of (i)–(iii),” (Pl.’s Responsive Br. 6), while Amneal asserts that “comprising” means “including, but not limited to” and thus supports additional steps to steps (i), (ii), and (iii), but does not otherwise shed light on the order of the steps, (Hr’g Tr. 21:8–18). Thus, the parties agree that the use of “comprising” in claim 1 allows “other steps between these steps,” and “other steps after these steps,” (*see id.* at 21:12–18; Pl.’s

Responsive Br. 6), but dispute whether the word “comprising” suggests that the steps may be performed out of the order as written.

The Court determines that the term “comprising” in claim 1 is not dispositive of the parties’ dispute in the sequence of the steps as written in claim 1. *See CyDex Pharms., Inc., v. Alembic Global Holding SA*, 2020 WL 6393918, at *9 (D. Del. Nov. 2, 2020) (concluding that the term “comprising” in the preamble meant that “the claims are not limited to the disclosed steps (i.e., steps (a), (b), and (c)) [and] [i]ntervening steps may occur between [the steps]”). This construction aligns with case law on “comprising” that says that “the term ‘comprising’ raises a presumption that the list of elements is nonexclusive . . . [h]owever, ‘[c]omprising’ is not a weasel word with which to abrogate claim limitations.” *Dippin’ Dots, Inc. v. Mosey*, 476 F.3d 1337, 1343 (Fed. Cir. 2007) (quoting *Spectrum Int’l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1380 (Fed. Cir. 1998)). Additionally, this construction aligns with the definition in the specification, which states that “comprise” and “comprising” are “open-ended linking verbs” and “any method that ‘comprises’ . . . one or more steps is not limited to possessing only those one or more steps and also covers unlisted steps.” (*See* ’453 Patent col. 65 l. 3–10.) The definition in the specification does not mention the effect of “comprise” or “comprising” on sequential ordering. Thus, the Court will not interpret “comprising” to impose sequential limitations on the steps in claim 1.

The Court next turns to the language of the claim to determine whether it requires sequential ordering. Regarding steps (i) and (ii), Amneal asserts that, because “[s]tep (ii) requires adding sodium benzoate to ‘the aqueous mixture[,]’ [t]he use of the definite article ‘the’ requires an antecedent basis in the claim, and the only possible antecedent basis is the ‘aqueous mixture’ provided in step (i)[, and] [t]hus, step (ii) requires adding sodium benzoate . . . specifically to the

‘aqueous mixture’ provided in step (i).” (Def.’s Opening Br. 3–4 (citing *Wi-Lan, Inc.*, 811 F.3d at 462–63 (emphasis in original)).)

Regarding steps (ii) and (iii), Amneal similarly argues that step (iii)’s requirement of “subjecting *the* first mixture to ultrasonic agitation,” necessarily refers to the “first mixture” formed in step (ii). (*Id.* at 4 (citing *Wi-Lan, Inc.*, 811 F.3d at 462–63 and *Chiesi USA Inc.*, 2021 WL 4843806 at *2–3) (emphasis in original).)

In *Wi-Lan, Inc.*, the Federal Circuit determined that the claim language required “randomizing” modulated data symbols (second element) to come before “combining” “the modulated data symbols” (third element) because “*the* modulated data symbols” in the third element referred to the modulated data symbols that were already randomized in the second element. 811 F.3d at 46 (emphasis in original). In *Chiesi*, where step (a) required “dissolving” a substance in a solvent to “form a first solution,” and step (b) required “mixing” an agent with “the first solution” to form a “second solution,” the district court determined that “as a matter of logic, before the first solution may be ‘mixed’ in step (b), it must first be ‘formed’ in step (a).” 2021 WL 4843806, at *2. The court also noted that the “plain language of the Patent provides no alternative method to obtain the first solution.” *Id.* at *2.

In addition to *Wi-Lan, Inc.*, and *Chiesi*, Amneal cites to several other cases to argue that in “factual circumstances similar to those here, courts have construed cases as requiring sequential performance.” (Def.’s Responsive Br. 3 (also citing *CyDex Pharms., Inc.*, 2020 WL 6393918, at *8–9 and *Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1308–10 (Fed. Cir. 2014), *overruled on other grounds by Williamson v. Citrix Online, LLC*, 792 F.3d 1339 (Fed. Cir. 2015).) In *CyDex Pharms., Inc.*, a district court construed a process claim where part (a) required formation of an “aqueous milieu”; part (b) required “the aqueous milieu” to form a “partially purified solution”;

and part (c) required “the partially purified solution” to be treated. 2020 WL 6393918, at *9. There, the court looked to both the claim language and several instances in the specification to determine that “[l]ogic require[d] that these steps be undertaken in this order.” *Id.* In *Apple Inc.*, the Federal Circuit upheld the district court’s interpretation that a claim comprising the steps of “forming an outer code,” “forming an inner code,” and “multiplying the outer code by the inner code” needed to be performed in order. 757 F.3d at 1309–10. There, the Circuit noted, “[t]he plain meaning of multiplying ‘the’ codes together is that the entire sequences are multiplied together after they have been formed . . . [and] [t]he more natural reading of the claim language supports the district court’s finding that the inner and outer codes must be fully formed before they are multiplied together.” *Id.* at 1309. In another case, not cited by Amneal, the Federal Circuit determined that, “each step of the method provides an antecedent basis for the steps that follow,” *e.g.*, that preparing “‘a’ timeslot” precedes a later step of “determining whether *the* timeslot is a current desired timeslot” *Hytera Commc’ns Co. Ltd. V. Motorola Solutions, Inc.*, 841 F. App’x 210, 218 (2021) (unpublished) (emphasis in original).

Similarly here, the language in claim 1 refers to actions in prior steps with the antecedent “the,” *e.g.*, in step (ii), “adding sodium benzoate to *the* aqueous mixture” refers back to the aqueous mixture “provid[ed]” in step (i), (’453 Patent col. 77 l. 49–52 (emphasis added)); and in step (iii), “subjecting *the* first mixture to ultrasonic agitation” refers to the “first mixture” that was formed in step (ii), (’453 Patent col. 77 l. 51–56 (emphasis added)). See *Wi-Lan, Inc.*, 811 F.3d at 462 (noting, “[s]ubsequent use of the definite articles ‘the’ or ‘said’ in a claim refers back to the same term recited earlier in the claim”); *Chiesi USA Inc.*, 2021 WL 4843806, at *2.

However, even accepting Amneal’s argument that the plain language of the steps in claim 1 provide the “logical and grammatical precursor for the subsequent step,” (Def.’s Opening Br. 3),

the Court declines to use claim language alone to construe this claim but rather also construes claim 1 “in view of the specification, of which [it is] a part.” *See Phillips*, 415 F.3d at 1315. The Court considers the specification to determine whether it sheds light on the sequential ordering of claim 1 because, looking only to the language of claim 1, it is not clear to the Court that the steps must be performed in order. This is not a case where, for example, the steps refer to prior steps in the past participle to show they have been completed, as in *Tuna Processors, Inc. v. Hawaii Intern. Seafood, Inc.*, 327 F. App’x 204, 209 (2009) (determining that the plain language of a claim demonstrated a temporal limitation on the steps of a smoking method because it referred to actions taken in prior steps in past participles, *e.g.*, “passing the produced smoke through a filter” preceded “cooling the smoke passed through the filter,” which preceded “smoking tuna meat . . . by exposure to the smoke cooled . . .”). *See also E-Pass Techs., Inc. v. 3Com Corp.*, 473 F.3d 1213, 1222 (Fed. Cir. 2007) (stating that, “because the language of most of the steps of its method claim refer to the *completed* results of the prior step, E-Pass must show that all of those steps were performed in order”) (emphasis added).

Rather, as a matter of logic, the Court could also construe steps (ii) and (iii) of claim 1 as occurring simultaneously if looking solely at the claim language, *e.g.*, “adding” the sodium benzoate to form a first mixture could occur simultaneously to “subjecting” the first mixture to ultrasonic agitation. *Cf. Amgen Inc. v. Hospira, Inc.*, 944 F.3d 1327, 1335 (Fed. Cir. 2019) (where claim 1 covered a particular “isolated” isoform and claim 27 covered a method for a composition comprising “preparing a mixture” of two or more isoforms of claim 1, finding that the isoforms used in preparing the mixture did not need to be already isolated when preparing the mixtures; rather, “the ‘mixtures’ . . . [could] be produced by ‘isolating selected [] isoforms *simultaneously*’”) (emphasis in original); *Interactive Gift Express, Inc.*, 256 F.3d at 1328, 1343 (in a claim covering

a “method for reproducing information . . . utilizing information manufacturing machines,” determining, “[l]ooking at the claim language, there is no reason why step one’s ‘providing’ of information to the [information manufacturing machine] must occur before step four’s ‘receiving the request reproduction code.’ . . . Logically, information could be sent after a request is made;” thus, the claim “cover[ed] real-time transactions in which the requested item of information is transmitted to the [information manufacturing machine] at or prior to the time it is requested by the consumer.”); *Globespanvirata, Inc. v. Tex. Instrument, Inc.*, 2005 U.S. Dist. LEXIS 5744, at *36–37 (D.N.J. Apr. 6, 2005) (determining that, while the words “based on” in subsequent step “suggest[ed]” sequential ordering because they referred to a prior step, the claim language did not impose “an absolute requirement that step (b) occurs after step (a) at all times”).

Moreover, even in cases where the Federal Circuit has determined that “the claim language logically requires that the process steps . . . be performed in sequence,” it has still looked to the specification in the claim construction inquiry. *Amgen, Inc. v. Sandoz, Inc.*, 923 F.3d 1023, 1028 (Fed. Cir. 2019) (citing *Mformation Techs., Inc.* and determining first that claim language logically required process steps, lettered (a) through (g), be performed in sequence because, for example, “expressing [a] protein” in a cell (step (a)) logically must occur before “lysing that cell” (step (b)); and then looking to the specification to determine that the specification “consistently” referred to the disputed terms as “separate steps,” which the court determined were process steps). In another case, after determining that “each step of the method provides an antecedent basis for the steps that follow,” and stating that, “[b]ecause we conclude that the claim language demonstrates the order of the steps, we need not look further into the specification,” the Circuit still looked to the specification. *Hytera Commc’ns Co. Ltd.*, 841 F. App’x. at 218–19 (citing *Altiris*, 318 F.3d at 1369). There, the Circuit determined that “the only embodiments are consistent with the plain

meaning of the claim in the order that is written, and we thus decline to construe the claim as allowing deviation from that order.” *Id.* at 219. The Circuit ultimately concluded, “[t]herefore, based on the language of the claim, *as supported by the embodiments in the specification*, we hold that the Board did not err by requiring the claim steps to be performed in the order written.” *Id.* (emphasis added).

In other Federal Circuit and district court cases, including the cases that Amneal cites, the courts looked to the specification after looking at the claim language. *E.g.*, *Wi-Lan, Inc.*, 811 F.3d at 462–63 (after discussing the plain language, also noting, “[t]he ordering requirement described above is consistent with the specification . . . [and] [e]very embodiment discussed in the specification randomizes the data symbols before combining them;” ultimately concluding, “[i]n summary, the intrinsic record requires that the symbols be modulated according to an invertible randomized spreading before being combined for transmission”); *Mformation Techs., Inc.*, 764 F.3d at 1400 (noting that its construction based on the claim language was consistent with the sole embodiment in the specification); *Apple Inc.*, 757 F.3d at 1309–10 (after concluding that the “more natural reading of the claim language supports” sequential ordering, turning to the specification, which further supported that “forming” inner and outer codes preceded “multiplying” the codes together; ultimately concluding, “[b]ecause it is supported by the plain meaning of the claim language and the specification, we affirm the district court’s claim construction”); *Loral Fairchild Corp. v. Sony Corp.*, 181 F.3d 1313, 1321 (Fed. Cir. 1999) (after determining that “the literal language of the claim” required “forming a first insulation layer” to precede “forming . . . barrier regions . . . aligned with the vertical edges of the insulation layer,” noting that both the specification and the prosecution history supported this order); *Mantech Env’t Corp. v. Hudson Env’t Servs., Inc.*, 152 F.3d 1368, 1376 (Fed. Cir. 1998) (finding that the sequential ordering of

steps was required where “the sequential nature of the claim steps [was] apparent from the plain meaning of the claim language *and nothing in the written description suggest[ed] otherwise*” (emphasis added); *Tuna Processors, Inc.*, 327 F. App’x at 209 (unpublished) (after determining that the plain language of the claim imposed a temporal limitation on the steps of a smoking method, considering whether the specification “dissuade[d] [the court] from reading a temporal limitation into the third step . . .”); *Chiesi USA Inc.*, 2021 WL 4843806, at *3 (considering the parties’ arguments on ordering with respect to the specification language and concluding that the specification language “merely discuss[ed] ways to mix the first and second solutions in step (b), and shed[] no light on the separate question of whether step (a) must precede step (b)”); *CyDex Pharms., Inc.*, 2020 WL 6393918, at *9 (after considering the claim language, noting that “[t]he specification discloses that same order of steps” and citing several instances in the specification). Thus, the Court will consider the specification of the ’453 Patent in its construction of claim 1.⁴

2. Specification

Azurity asserts that the specification does not teach that the actions of claim 1 must be performed in a specific sequence, (Pl.’s Opening Br. 7), while Amneal, asserts that the specification “repeatedly and uniformly uses the same operative logic and grammar used in the claims,” (Def.’s Opening Br. 4).

⁴ Amneal also relies on *E-Pass Techs., Inc.* and *TALtech Ltd.* (Def.’s Opening Br. 2–3); 473 F.3d at 1222; 279 F. App’x at 978 (unpublished). However, the weight of the authority supports considering the specification, even when “the sequential nature of the claim steps is apparent from the plain meaning of the claim language,” to see if the specification is consistent with the claim language. *Mantech Env’t Corp.*, 152 F.3d at 1376; *see also Amgen, Inc.*, 923 F.3d at 1028–29; *Loral Fairchild Corp.*, 181 F.3d at 1321; *Mformation Techs., Inc.*, 764 F.3d at 1400; *Wi-Lan, Inc.*, 811 F.3d at 462–63; *Apple Inc.*, 757 F.3d at 1309–10; *Tuna Processors, Inc.*, 327 F. App’x at 209; *see also generally Vitronics Corp.*, 90 F.3d at 1582 (noting that the specification “is the single best guide to the meaning of a disputed term”).

In cases where the specification is consistent with the claim language demonstrating that the steps are to be performed in order, courts have construed process claims to require sequential ordering. This is true of the cases cited by Amneal. *See, e.g., Wi-Lan, Inc.*, 811 F.3d at 463 (noting that “[t]he ordering requirement described [in the claim language] . . . is consistent with the specification”); *Apple Inc.*, 757 F.3d at 1309–10; *Chiesi USA Inc.*, 2021 WL 4843806, at *3; *CyDex Pharms., Inc.*, 2020 WL 6393918, at *9.

In cases where the specification contemplates the performance of the steps in a different order than that recited in the claim language, courts have determined that no ordering is required. *See, e.g., Interactive Gift Express, Inc.*, 256 F.3d at 1343–44 (in construing whether “providing” information must precede “receiving” a request reproduction code, where two embodiments showed “the ‘providing’ of information is performed after ‘receiving the request reproduction code,’” finding that the steps did not need to be performed sequentially; also noting that this is true despite the fact that “the specification describes these two non-preferred embodiments as impractical and uneconomical”); *Globespanvirata, Inc.*, 2005 U.S. Dist. LEXIS 5744, at *36–37 (where the court construed whether a “calculating step” needed to be performed before the “sorting step,” noting that “the specification describe[d] a dynamic system in which multiple carriers are acting in concert,” and “[t]hus, it [was] possible that ‘the calculating step’ [was] being performed before ‘the sorting step’ at any given time”).

Here, the Court finds that, with respect to step (i), the specification is consistent with the claim language demonstrating that step (i) is to be performed before steps (ii) and (iii). Logically, before steps (ii) or (iii) can occur, the “aqueous mixture” in step (i) must be “provided.” Further, Azurity does not point to embodiments or examples, as it does with steps (ii) and (iii), to support its argument that the aqueous mixture can be provided at any time. Thus, this step is similar to the

steps in *Chiesi*, where the court determined that the plain language of the claim provided that the steps of the claim be performed in order because “as a matter of logic, before the first solution may be ‘mixed’ in step (b), it must first be ‘formed’ in step (a),” and then further determined that the specification “shed[] no light on the separate question of whether step (a) must precede step (b).” 2021 WL 4843806, at *2. Similarly, here, the plain language of step (i)’s “providing an aqueous mixture” demonstrates that step (i) should precede the other two steps; and, the Court’s review of the specification does not suggest otherwise.⁵ (’453 Patent col. 77 l. 49–57); see *Chiesi USA Inc.*, 2021 WL 4843806, at *2–3.

By contrast, steps (ii) and (iii) are more similar to a “continuous process,” where “a process step does not need to be complete before another step begins,” and which has been recognized by the Federal Circuit in *Kaneka Corp. v. Xiamen Kingdomway Grp. Co.*, 790 F.3d 1298, 1306–07 (Fed. Cir. 2015). In *Kaneka*, the Circuit considered several method claims, including: (1) claim

⁵ Azurity argues that the prosecution history suggests that “adding the sodium benzoate” (step (ii)) could occur before “providing an aqueous mixture” (step (i)) because, in the Response to the Non-Final Office Action dated June 25, 2019, the patentee noted, “a skilled artisan would appreciate that parameters such as the duration of the sonication, the frequency of the soni[c]ation, and *the addition sequence of the salt forming agents and surfactants can be adjusted* to control the particle size.” (Response to the Non-Final Office Action dated June 25, 2019, AZU_KAT_0001113 (emphasis added).) According to Azurity, because “salt forming agents” include sodium benzoate, this suggests that the patentee understood the invention to allow sodium benzoate to be added to the tank before the aqueous mixture. (Hr’g Tr. 16:16–17:13.) Even if the Court interpreted the Response to mean that the inventor contemplated adding sodium benzoate to the tank before providing the aqueous mixture, the Court does not find this single statement persuasive to overcome the plain language indicating that step (i) comes first, and the specification providing no embodiments or examples that indicate otherwise. Cf. *Chiesi USA, Inc. v. Aurobindo Pharma USA, Inc.*, 2021 WL 4860327, at *6 (D.N.J. Oct. 19, 2021) (even where “prosecution statements [varied] from the characterizations made in the specification,” declining to find that these statements “overc[a]me the weight of the specifications repeated descriptions of the invention”) (citing *Phillips*, 415 F.3d at 1317, which states, “because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes”). Accordingly, the Court will not determine that step (ii) can come before step (i) based on this statement made in the prosecution history.

22, which required “disrupting” cells to obtain a reduced coenzyme, “oxidizing” the coenzyme, and “then extracting the oxidized coenzyme . . .”; and (2) claim 33, which was the same but recited the extracting step before the oxidizing step, *i.e.*, “disrupting” cells to obtain a reduced coenzyme, “extracting the reduced coenzyme,” and “oxidizing the extracted reduced coenzyme.” 790 F.3d at 1301–02. The Circuit determined that “*some* oxidation must occur before the extraction step in claim 22 or after the extraction step in claim 33,” but declined to find that “the claimed order require[d] that each step occur independently or separately.” *Id.* at 1306. With respect to claim 33, the Circuit determined that, “the extraction step . . . does not have to be complete before the oxidation step begins as long as the oxidation step is applied to at least some extracted product.” *Id.* at 1307. Likewise, with respect to claim 22, the Circuit determined, “[b]ecause the oxidation step indicates that oxidation is carried out on the product from the previous disruption step in claim 22, some action resulting in oxidation must occur after some product from the disruption step forms and before the extraction step in claim 22 begins.” *Id.* In sum, the Circuit rejected the district court’s construction that “all or substantially all” of the coenzyme must be oxidized during the oxidation step and determined, “[b]ecause the claims read on a continuous process, a process step does not need to be complete before another step begins,” and “it is not required that any one step be carried out separately or independently of any other step.” *Id.*

Here, the specification indicates that ultrasonic agitation may be “initiated” before or simultaneously to the addition of sodium benzoate to form the first mixture in step (ii). For example, Example 2 discusses the effect of polysorbate 80 on the formation of amlodipine benzoate in stainless steel containers and explains how the “polysorbate containing batches [] were prepared.” (’453 Patent col. 69 l. 60–61.) In the Example, the batches are prepared by adding purified water to a stainless-steel sonication tank, initiating mixing, adding polysorbate 80, rinsing

the polysorbate container and then adding the rinse to the tank, stirring the solution for ten minutes and adding amlodipine besylate to the tank, and rinsing the amlodipine container and adding the rinse to the tank. (*Id.* col. 69 l. 60–col. 70 l. 16.) The Example then states, “[t]he solution/suspension was stirred for 10 minutes *then sonication was initiated* (40 kHz frequency, 280 watts) *and sodium benzoate was added to the tank*. The sonication was discontinued after 10 minutes and the mixing continued for an additional 20 minutes.” (*Id.* col. 70 l. 15–21 (emphasis added).) Examples 4, 5, and 6 use this same process to make batches, with variations that do not pertain to the order of the steps, *e.g.*, length or frequency of sonication. (*See id.* col. 71 l. 62–65; *id.* col. 72 l. 16–22; *id.*, col. 72 l. 45–50.)⁶

However, while Example 2 suggests that ultrasonic agitation may be initiated before or simultaneously to the addition of sodium benzoate, the claim language and specification indicate that some ultrasonic agitation must occur to “the first mixture.” Specifically, the plain language stating that “the first mixture” must be “subject[ed] to” ultrasonic agitation and the Examples indicating that ultrasonic agitation continues after the addition of sodium benzoate demonstrate that, while ultrasonic agitation may be initiated before the first mixture is formed, it must at some point apply to the “first mixture.” (’453 Patent col. 77 l. 54–57 (plain language of claim 1 stating as step (iii), “subjecting the first mixture to ultrasonic agitation . . .”); col. 67 l. 33–38 (noting, “[t]he salt forming agent was then added to the suspension along with a pH adjusting agent if needed, and ultrasonic agitation at 40 kHz was applied for 30 minutes . . .”); col. 70 l. 16–21

⁶ The Court notes Amneal’s argument that the Examples in the specification are less informative as to how the inventor intended to practice his invention than the embodiments. (*See* Hr’g Tr. 38:4–39:18.) Amneal does not point to a case that suggests that the Court cannot consider the Examples. (*Id.* at 39:24–40:4.) Moreover, in its Opening Brief, Amneal cites to the Examples in support of its arguments that sequential ordering is required and notes that the Examples are “examples in the specification of preparation processes.” (Def.’s Opening Br. 4–6.) Accordingly, the Court considers the Examples as relevant intrinsic evidence in the construction of claim 1.

(noting that “sonication was initiated . . . and sodium benzoate was added to the tank,” and stating thereafter, “sonication was discontinued after 10 minutes”); col. 71 l. 31–36 (noting, “sonication . . . was continued for 10 minutes after the sodium benzoate addition”). Step (iii)’s ultrasonic agitation compares to the “oxidizing” and “extracting” steps in *Kaneka* because there, the Circuit determined that “the extraction step . . . does not have to be complete before the oxidation step begins as long as the oxidation step applies to at least *some* extracted product.” *See* 790 F.3d at 1307 (emphasis in original). Thus, as the Federal Circuit determined in *Kaneka* that the “oxidation step is applied to at least *some* extracted product,” here, at least some ultrasonic agitation must apply to the first mixture. *See id.* (emphasis in original).

Azurity argues that “[t]he specification explicitly contemplates performing the ultrasonic agitation before, during, and after the amlodipine besylate and sodium benzoate are mixed together.” (Pl.’s Responsive Br. 8 (citing ’453 Patent col. 2 l. 30–37, col. 42 l. 52–col. 43 l. 5).)

The specification language to which Azurity refers says:

In some embodiment of a process for preparing amlodipine benzoate, the first mixture is mixed before being subjected to ultrasonic agitation. In some embodiment of a process for preparing amlodipine benzoate, the first mixture is mixed while being subjected to ultrasonic agitation. In some embodiment of a process for preparing amlodipine benzoate, the first mixture is mixed after being subjected to ultrasonic agitation.

(’453 Patent col. 2 l. 30–37.) These statements refer to the ultrasonic agitation in relation to when the first mixture may be “mixed.” There is no “mixing” step listed in steps (i), (ii), and (iii). Rather, step (ii) discusses how to “form” the first mixture by adding sodium benzoate to the aqueous mixture. (*See id.* col. 77 l. 51–52.) Thus, this language pertains to when the “first mixture,” having already been formed in step (ii), may be mixed. The fact that the specification contemplates a “mixing” step supports the parties’ agreed-upon construction that claim 1 includes

additional steps to (i), (ii), and (iii), (*see* Hr’g Tr. 21:12–18; Pl.’s Responsive Br. 6; Discussion *supra* IV.C.1). This specification language is also consistent with the Court’s construction that ultrasonic agitation is a “continuous process step” as discussed above.

Accordingly, the claim language and the specification instruct the Court that claim 1 requires step (i) (providing an aqueous mixture) to occur before steps (ii) and (iii); that ultrasonic agitation may be initiated before or simultaneously to adding the sodium benzoate in step (ii), but there must be at least some ultrasonic agitation that occurs after the addition of sodium benzoate in step (ii) in order to “subject[] the first mixture to ultrasonic agitation” (step (iii)). (’453 Patent col. 77 l. 53–56.) The Court finds that this claim construction preserves the claimed order of steps (i), (ii), and (iii), but does not exclude ultrasonic agitation from also occurring before step (ii). *See Kaneka*, 790 F.3d at 1306. This construction is consistent with the word “comprising” as well as the specification, both which contemplate claim 1 to include additional steps and variations to the steps listed in claim 1. (’453 Patent col. 77 l. 48; *see also e.g., id.* (col. 4 l. 22–43 (noting that some embodiments include additional steps to steps (i), (ii), and (iii)).)

3. Prosecution History

While the claim language and specification are sufficient to construe claim 1, the Court considers the parties’ arguments with respect to prosecution history.

Amneal argues that the prosecution history suggests that the patentee embraced a “sequential rubric” when amending certain claims during the patent application to specify that “a second surfactant” was added “into the second mixture,” (Conroy Cert., AMKAT0020335, ECF No. 58-1), and those additional components were introduced by “adding the second mixture into a third mixture” containing those additional components, (*see id.* AMKAT0020336–37). (Def.’s Opening Br. 7.) The Court first notes that two of these claims were ultimately dropped from the

prosecution and are not part of the final patent. (*See* '453 Patent col. 77 l. 44–col. 79 l. 14.) Additionally, the use of the words “first” and “second” does not necessarily indicate sequential ordering. The Federal Circuit has noted that “[t]he use of the terms ‘first’ and ‘second’ is a common patent-law convention to distinguish between repeated instances of an element or limitation.” *3M Innovative Properties Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1371 (Fed. Cir. 2003) (finding that the use of the terms “first . . . pattern” and “second . . . pattern” is equivalent to a reference to ‘pattern A’ and ‘pattern B,’ and should not in and of itself impose a serial or temporal limitation onto claim 1”).

Azurity asserts that, based on the Notice of Allowability, “the examiner characterized the Allowable Subject Matter as ‘suspensions comprising particles having a median diameter of 5-40 μ m and comprising amlodipine benzoate and other additives, wherein amlodipine benzoate is produced *in situ* by mixing amlodipine besylate, sodium benzoate and other additives, and wherein said suspensions are stable at 25 °C for at least 12 months.” (Pl.’s Responsive Br. 10 (quoting Not. of Allowability, Pl.’s Ex. B, AZU_KAT0001965, ECF No. 56-6).) Thus, Azurity argues, the examiner did not understand the order of the recited actions in claim 1 to be a critical part of the invention. (*Id.* at 10–11.) However, the fact that the examiner characterized the Allowable Subject Matter as such does not “overc[o]me the weight of the specifications repeated descriptions of the invention.” *See Chiesi USA, Inc.*, 2021 WL 4860327, at *6. Accordingly, the Court does not rely on this prosecution history to construe claim 1.

D. *Extrinsic Evidence*

Finally, the parties dispute whether the Court should look to extrinsic evidence, in the form of the Little Declaration, to construe claim 1. (*See* Mot. to Strike Little Decl. 2, ECF No. 65-1; Opp’n to Mot. to Strike Little Decl. 2, ECF No. 72.) Amneal filed a Motion to Strike the Little

Declaration, (ECF No. 65), and raised several issues concerning his statements at the hearing, (Hr'g Tr. 32:9–33:10). The Court does not need to reach this issue because, based on the foregoing, the meaning of claim 1 is clear based on the claim language and specification. *See Vitronics Corp.*, 90 F.3d at 1583 (noting that “it is improper to rely on extrinsic evidence” when “an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term”). Thus, the Court does not consider the Little Declaration. Amneal’s Motion to Strike is dismissed as moot.

V. CONCLUSION

For the foregoing reasons, the Court construes the disputed term of claim 1 in United States Patent No. 10,799,453 as follows: Step (i) must occur before steps (ii) and (iii); ultrasonic agitation may be initiated before or simultaneously to adding the sodium benzoate in step (ii); at least some ultrasonic agitation (step (iii)) must occur after step (ii) in order to “subject[] the first mixture” to ultrasonic agitation. Additionally, Amneal’s Motion to Strike (ECF No. 65) is dismissed as moot because the Court does not need to rely on extrinsic evidence in this claim construction.

ORDER

Accordingly, for the foregoing reasons,

IT IS, on this 24th day of August, 2022,

ORDERED that the disputed term of claim 1 in United States Patent No. 10,799,453 is construed as follows: Step (i) must occur before steps (ii) and (iii); ultrasonic agitation may be initiated before or simultaneously to adding the sodium benzoate in step (ii); at least some ultrasonic agitation (step (iii)) must occur after step (ii) in order to “subject[] the first mixture” to ultrasonic agitation; and it is further

ORDERED that Amneal’s Motion to Strike (ECF No. 65) is **DISMISSED AS MOOT**.

A handwritten signature in black ink that reads "Georgette Castner". The signature is written in a cursive, flowing style. Below the signature is a horizontal line.

GEORGETTE CASTNER, U.S.D.J.